



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/580,613

03/08/2007

Leif Hermansson

102881-102

3900

27267

7590

07/26/2010

WIGGIN AND DANA LLP
ATTENTION: PATENT DOCKETING
ONE CENTURY TOWER, P.O. BOX 1832
NEW HAVEN, CT 06508-1832

EXAMINER

BARHAM, BETHANY P

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

07/26/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/580,613	Applicant(s) HERMANSSON ET AL.	
	Examiner BETHANY BARHAM	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 21-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20, 36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

Receipt of Applicant's response and amended claims filed on 05/27/10 is acknowledged. Claims 1-37 are pending and claims 21-35 remain withdrawn. Claims 1-20 and 36-37 are rejected.

Due to Applicant's claim amendments the previous 112 rejections and 102 rejections over Cini et al, '777, '599 and '903 are hereby withdrawn. All other rejections of record are hereby maintained.

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-20 and 36-37 are rejected under 35 U.S.C. 102(a) as being anticipated by US 2003/0215484 ('484).

Art Unit: 1615

The instant claims are directed to a coated implant for in vivo-anchoring to a biological tissue or another implant, which coated implant comprises an implant having a pre-treated surface and on said pre-treated surface one or more layers of mainly non-hydrated chemically bonded ceramic material, characterized in that each layer of said ceramic material independently comprises a first binder phase selected from the group consisting of aluminates, silicates, phosphates, sulphates and combinations thereof, and that said ceramic material is chemically and/or mechanically bound to said implant, and in that the coated implant additionally is coated with a ceramic paste comprising a powdered calcium-based binder of aluminate and/or silica and a hydration liquid.

- '484 teaches a ceramic coating on a substrate that is preparing by pretreating the substrate and applying at least one layer of non-hydrated powder mixture on the substrate and application of second layers is also taught (abstract, claim 1, [0023-0024]). According to '484 several layers of non-hydrated powder can be applied and then finally the implant can be hydrated ([0044-0051], Example) (meeting the limitations of instant claims 1-4). Note the same components are taught by '484 as instant claimed, as a hydration liquid of water applied to the multi-layered non-hydrated ceramic layers would naturally hydrate the outer layer first, and for a short period of time leave the inner layers non-hydrated until the reaction proceeds [0035, 0060-0062]).
- '484 teaches various CA stoichiometries, CA or CA₂ or C₁₂A₇, etc [0059] of 0.5-20 microns [0033-0034] and Ra values of 0.1-10 microns, specifically 0.6-0.7

Art Unit: 1615

[0039, 0056]. Porosities of 30-40% are taught [0060] (meeting the limitations of instant claims 5, 7-9 and 11).

- '484 teaches including phosphates or salts thereof in the coatings [0052] (meeting the limitations of instant claims 6 and 36).
- '484 teaches thicknesses of 20-50 microns, and Examples of 22 micron thickness or less than 10 micron particle sizes are taught [0056-0059] (meeting the limitations of claims 10, 12 and 18-20).
- '484 teaches various implants such as medical implants, bone implants, orthopedic implants, etc which are made of ceramic, metallic or polymeric material such as titanium, etc [0044,0056] (meeting the limitations of claims 13-15 and 37).
- '484 teaches that the surface is oxidized with aluminate [0056] (meeting the limitations of claims 16-17).

NEW:

Claims 1-20 and 36-37 are rejected under 35 U.S.C. 102(a) as being anticipated by US 2004/0146752 ('752).

- '752 teaches a multilayered coating on a substrate such as an implant comprising a non-hydrated ceramic powder binder phase mixture or several mixtures with on or more different layers on top of each other (abstract, [0010-0012]). '752 teaches that pretreatment of the substrate and that calcium aluminates are preferred for the powder mixtures [0025, 0036-0037] and

Art Unit: 1615

according to '752 removal of residual water/organic solvents is carried out and that the non-hydrated layers can be compacted prior to the final hydration [0043-0045, 0052-0056]. According to '752 the final step is hydration of the coating layers with hydraulic component with water or evaporated water [0030-0031] (meeting the limitations of instant claims 1-4).

- '752 teaches various CA stoichiometries, CA or CA₂ or C₁₂A₇, etc [0037] of below 10 microns, or 2 microns [0044, 0068]. Porosities of 30-45% are taught [0045] (meeting the limitations of instant claims 5, 7-9 and 11).
- '752 teaches including phosphates or salts thereof in the coatings [0038-0039] (meeting the limitations of instant claims 6 and 36).
- '752 teaches thicknesses of 0.1-500 microns, and preferably less than 50 microns [0056] (meeting the limitations of claims 10, 12 and 18-20).
- '752 teaches various implants such as medical implants, bone implants, orthopedic implants, etc which are made of ceramic, metallic or polymeric material such as titanium, etc [0011-0012, 0035 and 0070] (meeting the limitations of claims 13-15 and 37).
- '752 teaches that the surface is oxidized with aluminate [0071] (meeting the limitations of claims 16-17).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

Art Unit: 1615

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 and 36-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There is no evidence in the instant specification that the “one or more layers of mainly non-hydrated chemically bonded ceramic material...and...the ceramic paste comprising a calcium-based binder of aluminate and/or silica and a hydration liquid” as claimed are capable of being made together with the “one or more layers of mainly non-hydrated chemically bonded ceramic material” remaining non-hydrated. Based on the instant disclosure, it is the examiner’s position that Applicants do not describe this invention in such a manner that would enable one of ordinary skill in the art to practice this invention without undue burden. In fact original claim 35 an implantation kit claims that the ‘ceramic powder and hydration liquid of the paste are kept separately’.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: (1) breadth of the claims; (2) nature of the invention; (3) state of the prior art; (4) amount of direction provided by the inventor; (5) the level of predictability in the art; (6) the existence of working examples; (7) quantity of experimentation needed to make or use the invention based on the content of the disclosure; and (8) relative skill in the art. All of the factors have been considered with regard to the claim, with the most relevant factors discussed below:

The breadth of claims: The instant claim 1 is directed to a coated implant for in vivo-anchoring to a biological tissue or another implant, which coated implant comprises an implant having a pre-treated surface and on said pre-treated surface one or more layers of mainly non-hydrated chemically bonded ceramic material, characterized in that each layer of said ceramic material independently comprises a first binder phase selected from the group consisting of aluminates, silicates, phosphates, sulphates and combinations thereof, and that said ceramic material is chemically and/or mechanically bound to said implant, and in that the coated implant additionally is coated with a ceramic paste comprising a powdered calcium-based binder of aluminate and/or silica and a hydration liquid. It is the examiner's position that this claim is not supported by the instant specification, as addition of a hydrated layer to the non-hydrated layers would naturally hydrate the non-hydrated layers.

The nature of the invention: The instant invention is directed to a coated implant for in vivo-anchoring to a biological tissue or another implant comprising "one or more layers of mainly non-hydrated chemically bonded ceramic material" and "coated with a ceramic paste comprising a calcium-based binder of aluminate and/or silica and a hydration liquid".

The state of the prior art: As set forth in 2003/0215484 A1 ('484), an implant coating can include layers of non-hydrated calcium aluminate powder and further teaches the

Art Unit: 1615

steps of drying/evaporating the solvent after deposition of the powder, compaction and as a final step according to '484 the layers can be hydrated ([0044-0046,0051], Example). According to '484 if a calcium aluminate powder is mixed with a water based solution a hardening process is initiated through a chemical reaction and the formation of hydrates occurs [0035]. The prior art does not teach that a non-hydrated layer remains non-hydrated in the presence of a hydration liquid, but rather that naturally a chemical reaction occurs to turn the non-hydrate into a hydrate. With a broad general disclosure, Applicants have not described how their invention would specifically be made and how the non-hydrated coating remains non-hydrated in the presence of an additional coating that contains a hydration liquid, in fact according to the kit in Applicant's disclosure the hydration liquid must be kept separate from the ceramic material. Given the instant disclosure, one of ordinary skill in the art would have to resort to trial and error experimentation in order to practice the invention commensurate in scope with the claims.

The amount of direction provided by the inventor: There is nothing in the specification that would indicate that the non-hydrated coating remains non-hydrated in the presence of an additional coating that contains a hydration liquid is not provided in the specification. Instead the instant specification teaches two components are to be in separate containers in the kit. As a result, one of ordinary skill in the art would have to revert to trial and error experimentation in order to practice the invention commensurate in scope with the instant claim set. With respect to the instant composition, there is a

Art Unit: 1615

substantial gap between a non-hydrated coating and a non-hydrated coating with an additional hydration liquid layer. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap.

The presence or absence of working examples: The example teaches that the CA-paste aqueous solution is not applied until directly before implantation as is accelerates curing of the calcium aluminate. Thus the end result of such a composition would be hydrated calcium aluminate absent a showing otherwise.

The quantity of experimentation: In the instant case, it is unclear that the non-hydrated coating remains non-hydrated in the presence of an additional coating that contains a hydration liquid (especially in light of the prior art that teaches a chemical reaction naturally occurs to turned the calcium aluminate into a hydrate). Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap. In order to utilize the invention as claimed, the skilled artisan would be presented with an unpredictable amount of experimentation. The instant disclosure is broad and generic. It is not clear what specific embodiments would be required in order for one of ordinary skill in the art at the time the invention was made to practice the instant invention commensurate in scope with the claims.

The relative skill of those in the art: the skill of one of ordinary skill in the art is very high, e.g., Ph.D. and M.D. level technology.

Response to Arguments

Applicant's arguments with respect to the instant claims have been considered but are not persuasive and are moot in view of the new grounds of rejection necessitated by applicants' amendments. Applicant argues that the prior art '484 teaches a subsequent step of hydration of the powdered layer and that there is no teaching or suggestion of a ceramic paste coating the implant. The Examiner respectfully points out that several coatings of cement powder of calcium aluminate that are non-hydrated and then further a step of hydration would naturally 'hydrate' the outer layer first and thus would naturally form the instant composition. Applicant has not indicated how the non-hydrated material instant claims remains non-hydrated in the presence of the paste and as such the prior art is believed to be equivalent to the instant claimed composition, since the outer layers of '484 and '752 would be hydrated first, prior to the inner layers of non-hydrated calcium aluminate.

Conclusions

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

Art Unit: 1615

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)272-6175. The examiner can normally be reached on M-F, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bethany Barham
Art Unit 1615

/S. TRAN/
Primary Examiner, Art Unit 1615